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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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PURDUE PHARMA L.P., et al.,

Trial

Plaintiffs,

00 Civ. 8029 (SHS)

v.

01 Civ. 2109 (SHS)

ENDO PHARMACEUTICALS, INC.,

01 Civ. 8117 (SHS)

Defendant.

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New York, N.Y.

June 4, 2003

10:10 a.m.

Before:

HON. SIDNEY H. STEIN

District Judge

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Kaiko - cross

1 Q. How about --

2 A. We talked about that yesterday. This is what it is.

3 Something else is what *it* is.

4 Q. How about further down in the secondary variables, "range
5 of doses to achieve stable regimen in the cumulative
6 distribution of final dose to achieve a stable regimen." Is
7 that ease of titration?

8 A. No.

9 Q. Not ease of titration. OK. Let's move on. Let's go to
10 Defendant's Exhibit 3738. This is a 1996 DPS poster abstract
11 form. Do you know what kind of document this is?

12 A. Yes.

13 Q. Is this a publication?

14 A. Yes -- it's an application for a publication.

15 Q. Do you see that the main author is P. LoRusso?

16 A. Yes.

17 Q. That is in fact P. Mucci-LoRusso?

18 A. Yes.

19 Q. You see in the text, the sixth line from the bottom, it
20 reports the time to stable pain control was 3.8, plus or minus
21 .5 for OCR -- that's oxycodone? OxyContin, I should say.

22 A. Yes.

23 Q. Is that correct? And 3.6 plus or minus 4 for -- and is the
24 "MCR" in fact MS Contin?

25 A. Yes.

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1 Q. Could you now turn to Defendant's Exhibit 4358. I'm sorry.
2 There is no need to.

3 Let's go to Defendant's Exhibit 4361.

4 I'm sorry. Just back up in your book. I would like
5 to ask you one question about 4358. You see you're indicated
6 as a recipient of a note from Dr. Goldenheim, but then there's
7 your memo down below, and in that you say, "as in my clinical
8 review of Kalso, 0303." Am I correct in stating that, as of
9 that time, you were quite familiar with another protocol and
10 clinical study of a person by the name of Kalso, which had the
11 indicator 0303 as the protocol?

12 A. Yes.

13 Q. And could you go to the last page of Defendant's Exhibit
14 4358. This is September of 1996. Isn't that correct?

15 A. Yes.

16 Q. And do you see in the third paragraph down, I believe, on
17 page 572294, it states, "CR oxycodone provided comparable
18 efficacy as CR morphine, with no significant differences in:
19 number of dosage adjustments, time to stable pain control,
20 degree of pain control, and use of rescue medication." Do you
21 see that?

22 A. Yes.

23 Q. Did you write that at that time?

24 A. That's characterized here as --

25 Q. My first question is, did you write it at this time? Is

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Kaiko - cross

1 this your language?

2 A. I don't remember exactly, so the only help I can give
3 myself is by seeing the context it's in. It says "BK draft
4 version." So I accept that that's what it is.

5 Q. "BK" refers to yourself?

6 A. Yes.

7 Q. Can we go to Defendant's Exhibit 4361. Is this the final
8 study report relating to Mucci-LoRusso that was submitted to
9 the FDA on February 20, 1997? It's Defendant's Exhibit 4361.

10 A. Yes.

11 Q. Could you turn to the page that is 187347.

12 A. Yes.

13 Q. It includes as one of the investigators Patricia
14 Mucci-LoRusso?

15 A. Yes.

16 Q. It shows a start date of June 1, 1994 and an end date of
17 December 27, 1995?

18 A. Yes.

19 Q. And on the next page, that ends in 48, it indicates that
20 you reviewed this paper?

21 A. Yes.

22 Q. Could you turn to the conclusions paragraph on page 75 of
23 the study report, page 187423.

24 A. Yes.

25 Q. This indicates a date of September 27, 1996.

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Kaiko - cross

1 A. Yes.

2 Q. Were you aware at that time that at least one of your
3 patent applications, the '295 patent application, was pending?

4 A. Yes.

5 Q. And I direct your attention to the third paragraph of the
6 conclusions. And I read it to you and ask whether this is your
7 recollection, your correct understanding that at the time as a
8 conclusion, final conclusion of the Mucci-LoRusso study, quote,
9 CR oxycodone was as effective as CR morphine in relieving pain
10 in cancer patients. The median time to achieve stable pain
11 control was two days with both treatments, and the number of
12 dose adjustments required in rescue medication used were
13 similar for both drugs. Do you recall that you were aware of
14 that at the time, in roughly September of 1996?

15 A. Yes, but I had indicated yesterday the study wasn't
16 designed to determine whether there was a difference or not.

17 Q. It wasn't designed as a titration study?

18 A. It wasn't designed to determine whether there was a
19 difference or not in terms of titration, that is correct.

20 Q. So that conclusion shouldn't be there. It shouldn't be
21 included in the conclusions portion?

22 A. This study did not either prove or disprove time to stable
23 pain control.

24 Q. Do you think it would have been information important for
25 the patent examiner to know in assessing whether you had in